UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF OHIO

EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION	MDL 2804
OPIATE LITIGATION	Case No. 17-md-2804
This document relates to:	Hon. Dan Aaron Polster
Track One Cases	

PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE LACEY KELLER'S OPINIONS AND PROPOSED TESTIMONY

July 31, 2019

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Plaintiffs submit this memorandum in opposition to Defendants' Motion to Exclude Lacey Keller's Opinions and Proposed Testimony.[1] Keller is a data-mining expert whose opinions relate to the inadequacy of manufacturer defendants' ("Manufacturers") suspicious order monitoring ("SOM") systems and their failure to satisfy their obligations under the Controlled Substances Act, 21 U.S.C. §§ 801 *et seq.* ("CSA"). Using her expertise in the science of data-mining, Keller applied certain industry standard metrics as well as defendants' own SOM compliance metrics to analyze data that was available to Manufacturers and demonstrated how using that data for SOM purposes would have identified orders of unusual size, frequency, or pattern. Defendants seek to exclude her testimony arguing that she does not answer any question at issue in the case and that some of her opinions are unsupported by evidence. Their motion should be denied because Keller's opinions are well-supported by the evidence and will help the fact finder answer questions that lie at the core of this litigation: whether Manufacturers had tools and data at their disposal that would have been effective in identifying orders of unusual size, frequency, or pattern and what the use of those tools and data would have revealed.

FACTS

The Context of Keller's Opinions

As set forth in Plaintiffs' Memorandum of Law in Support of Motion for Partial Summary Adjudication with Respect to Defendants' Duties Under the Controlled Substances Act (Dkt # 1887-1) ("CSA-Duties Brief")[2], the CSA establishes a "closed system" for the manufacture, sale, and distribution of prescription opioids. In order to maintain this "closed system" (and in exchange for the privilege of dealing in controlled substances), Defendants are required to maintain "effective controls against diversion." *See Masters Pharm., Inc. v. Drug Enf't Admin.,* 861 F.3d 206, 212-213 (D.C.

[1] A copy of Keller's Report and Errata ("Report") appears at Dkt # 2000-7 (sealed). An Addendum to the Report is provided here as Exhibit A, and Corrections to the Report are attached as Ex. B. Exs. A & B are exhibits to Keller's deposition. Lacy Keller Dep. (06/13/19), Dkt. # 1963-13 (sealed).

[2] Plaintiffs filed two separate motions regarding suspicious ordering monitoring, one (the "CSA-Duties" motion) addressing the scope of Defendants' duties and the other (the "CSA-Compliance" motion, discussed below), setting forth the undisputed evidence that Defendants failed to comply with those duties.

Cir. 2017); *Southwood Pharm., Inc.; Revocation of Registration*, 72 FR 36487-01, 36500, 2007 WL 1886484 (DEA July 3, 2007). They must (i) design and operate a system to identify suspicious orders; (ii) report to the DEA suspicious orders "when discovered"; and (iii) decline to ship an order identified as suspicious unless, through due diligence, they are able to determine that the suspicious order is not likely to be diverted. *See Masters Pharm.*, 861 F.3d at 212-213. *See also Southwood Pharm.*, 72 FR 36487-01, 36500; 21 C.F.R. § 1301.74; Ex. C (Letter from DEA to Registrants, Dec. 27, 2007). "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

As Plaintiffs have detailed elsewhere, the Manufacturers had a wealth of data available to them to assist them in identifying suspicious orders. *See* Memorandum of Law in Support of Plaintiffs' Motion for Partial Summary Adjudication that Defendants Did Not Comply with Their Duties under the Federal Controlled Substances Act to Report Suspicious Opioid Orders and Not Ship Them (Dkt # 1924-1) ("CSA-Compliance Brief"). This data gave Manufacturers nearly complete visibility about the supply chain for their opioids, information that they could have used—but for the most part did not use—to assist them in maintaining effective controls against diversion.

The Compliance Metrics Available to Manufacturers to Identify Suspicious Orders

Manufacturers and distributors used compliance metrics (sometimes called "algorithms") for the purpose of identifying suspicious orders based on the "unusual size" criteria.[3] Keller considered those same metrics in her analysis. As discussed more fully in the CSA-Compliance Brief, the consistent application of these metrics would have flagged millions of prescriptions and thousands of transactions in the relevant time period, but Manufacturers consistently failed to report more than a

[3] For example, "Mallinckrodt: Rolling Average ([redacted])" was applied by Mallinckrodt to identify buyers whose purchases within a 30-day period were [redacted] their average purchases over the previous [redacted] months. Keller Rep. Dkt. # 2000-7at 19.

handful of suspicious orders. Keller's analysis shows what would have been revealed to Manufacturers if they had applied the various compliance metrics to the available data.

Keller's Qualifications

Defendants do not question Keller's qualifications as a data-mining expert—and with good reason. She holds Master of Economics degree from the New School for Social Research, a Bachelor of Business Administration degree from Washburn University, and a Certificate in Data Science from General Assembly. She is the Managing Director for Data-mining & Analytics with Gryphon Strategies, Inc., a leading investigation firm, where she created and directs their data-mining and analytics division. In her current role, she advises financial and law firms on the use of data for investments and investigations. Prior to founding Gryphon's Data-mining & Analytics Division, she founded and directed the Research and Analytics Department for the New York State Office of the Attorney General ("NYAG"), where she served from 2013 to 2017.

Keller's primary role at the NYAG's office was to help the office identify areas for investigation using data. In this role, she was frequently asked to investigate subject areas in which she had no prior expertise. To accomplish such assignments, Keller educated herself on the subject areas through research and discussions with subject matter experts. Included among such assignments was extensive work on issues related to opioids. For example, while at the NYAG, she developed and managed the Community Overdose Prevention Program, which uses data analytics to determine how best to deploy life-saving naloxone across New York State. Chief among the datasets she used for opioids-related work was the DEA's ARCOS data.

Keller's Opinions

For this litigation, Keller was asked to analyze various data sets using a variety of metrics that Manufacturers had available to them. She does not offer opinions as to whether Defendants' SOM programs complied with the CSA; rather, her opinions are limited to analyzing what Defendants could have done in their SOM programs with the data available to them, what they actually did, and what

they would have found had they applied any or all of the metrics she used. This data analysis provides a foundation for other experts—and the fact-finder—to draw conclusions about the adequacy of Defendants' suspicious order monitoring under the law. Keller's analysis is also relevant to the question of causation, because, by identifying the suspicious orders that were there to be found, and linking them to specific diversion points (i.e., prescribers and pharmacies) in Summit and Cuyahoga Counties, Keller's analysis demonstrates what would or could have occurred but for Defendants' failure to identify, report, and halt suspicious orders

In Part One of her Report, Keller analyzes IQVIA Xponent data, which provides a representative sample of opioid prescriptions filled, including the doctor who wrote the prescription and the drug prescribed. This data was available to the Manufacturers; most of them in fact purchased it during the relevant period in order to assess the effectiveness of their own sales efforts and to focus their sales efforts on healthcare providers who prescribed a high volume of opioids. Keller Rep Dkt # 2000-7at 27-28. By analyzing this data, Keller was able to identify physicians in Summit and Cuyahoga Counties whose prescribing activity would have been flagged by application of defendants' SOM metrics. She was also able to determine the number of prescriptions, dosage units, and morphine milligram equivalents ("MMEs") that those physicians' prescriptions represented. Her analysis shows that IQVIA data could have been used by Manufacturers to identify millions of prescriptions representing hundreds of millions of dosage units in Summit and Cuyahoga Counties.

Keller also provides six case studies of high opioid-prescribing physicians in Summit or Cuyahoga Counties. Confirming the reliability of Keller's methodology, all of them triggered one or more of the metrics used. For example:

> Dr. Guang Yang … tripped all prescriber-applied compliance metrics. … Yang wrote [almost 40,000] opioid prescriptions in 2011 … .If Yang had worked 24 hours a day for all 365 days of 2011, he would have written an average of almost [110] prescriptions per day, spending [13] minutes per patient—all while not sleeping.

Keller Rep Dkt # 2000-7at 36-37 & Ex. B. There is no evidence that any Manufacturer reported Yang to the authorities. Quite the opposite: Yang was a target of Manufacturers' intensive marketing—they made at least 562 sales calls on Yang between 2006 and 2017. Keller Rep Dkt # 2000-7at 36-37.

Keller also analyzed what would have happened if a manufacturer with a comparatively small market share had reported suspicious orders flagged by the metrics. She demonstrated that if Janssen—the manufacturer with the second smallest market share among Manufacturers in Summit and Cuyahoga Counties—had reported flagged orders, and if the physicians responsible for those orders had been brought to the attention of the authorities, prescriptions for millions of dosage units could have been stopped in Summit and Cuyahoga Counties, because action by the authorities against those prescribers would have stopped not only the fulfillment of prescriptions of Janssen's opioids, but also prescriptions by the same prescriber for other Manufactures' opioids.

In Part Two of her report, Keller analyzes two other types of data available to the Manufacturers so-called "chargeback" and "867" data. "Chargeback" data provides Manufacturers details about distributors' sales to downstream customers, including pharmacies, hospitals, and other dispensers; it was provided to Manufacturers in connection with arrangements whereby distributors could charge manufacturers back for unsold drugs or drugs sold at lower than expected prices. Keller Rep Dkt # 2000-7at 11. Information about opioid shipments is further reflected in "867" data, which provides details about distributors' sales to their downstream customers, broken down by zip code and type of outlet, and it was used by some Manufacturers in investigations of suspicious prescribers and downstream customers. *Id.* at 13-14, 22, 27, 58-59, 92, 96-97.

Using chargeback and 867 data, Keller was able to identify pharmacies in Summit and Cuyahoga Counties whose buying activity would be flagged by the SOM metrics. She was also able to determine the number of transactions that would be flagged, the number of dosage units that those chargebacks represented and which Manufacturers' sales were associated with the flagged transactions.

Her analysis shows that Manufacturers could have detected the suspicious activity of specific pharmacies—examples of which are profiled in her report—and, had they complied with their legal obligations, they would have stopped hundreds of millions of dosage units from being dispensed in Summit and Cuyahoga Counties.

Keller provides six case studies of individual pharmacies. For example:

> Located … in Cleveland, Marc's 23PU was flagged many times by the methodology. … A single location of a pharmacy chain, Marc's 23PU purchased enough opioids to supply Cuyahoga County with almost 2 million dosage units in just eight years, according to ARCOS data. … In November 2014, Cardinal Health noted that Marc's had been over its ordering threshold limit more than 80% of the time they ordered from the distributor. Marc's triggered nine of the ten metrics involved in this methodology.

Keller Rep Dkt # 2000-7at 63-66. As with the physician case studies, the pharmacy case studies confirm the reliability of the metrics that Keller employed. Finally, Keller performed an analysis of Mallinckrodt's shipments of orders they deemed "peculiar," but failed to report as suspicious or halt shipment of them, in order to estimate the extent to which such orders ended up in Summit and Cuyahoga Counties.

The results of Keller's analysis are enlightening: had Manufacturers applied data analytic techniques similar to those used by Keller, that analysis would have identified suspicious orders in Cuyahoga and Summit Counties responsible for millions of opioid prescriptions, thousands of transactions, millions of dosage units, and billions of MMEs. In the aggregate, the suspicious orders that Manufacturers could have identified were responsible for more than half of all opioid prescriptions, transactions, dosage unites, and MMEs written and filled in Summit and Cuyahoga Counties in the periods 1997-2006 and 2008-2017. Keller's analysis also shows that closer analysis of the flagged transactions would have identified by name numerous doctors and pharmacies in Summit and Cuyahoga Counties—not limited to those profiled in her report—who were connected to highly suspicious transactions.

ARGUMENT

I. KELLER'S METHODOLOGY IS RELIABLE AND WOULD ASSIST THE FACT-FINDER

A. Keller's Methodology Is Reliable

Data-mining is generally accepted in the scientific community and routinely used both in the pharmaceutical industry and among regulators worldwide. *See In re Abilify (Aripiprazole) Prod. Liab. Litig.*, 299 F. Supp. 3d 1291, 1316 (N.D. Fla. 2018); *Rheinfrank v. Abbott Labs., Inc.*, No. 1:13-cv-144, 2015 WL 13022172, *13 (S.D. Ohio Oct. 2, 2015); *In re Fosamax (Alendronate Sodium) Prod. Liab. Litig.*, Nos. 11-5304, 08-08, 2013 WL 1558690, *8 (D.N.J. Apr. 10, 2013); *In re Yasmin and YAZ (Drospirenone) Mktg., Sales Practices and Prod. Liab. Litig.*, No. 3:09–md–02100–DRH–PMF, 2011 WL 6302573, *17 (S.D. Ill. Dec. 16, 2011)

To be clear, Keller does not claim to be an expert in SOM compliance. She offers no opinion on whether the orders flagged by her analysis were actually "suspicious" within the meaning of the applicable regulations. Rather, she is a data-mining expert who has marshaled the relevant data and applied appropriate metrics to determine whether the metrics flagged the transactions to which they were applied. Contrary to defendants' argument, a data-mining expert "need not … have direct experience with the precise subject matter or product at issue." *Jackson v. E-Z-GO Div. of Textron, Inc.*, 326 F. Supp. 3d 375, 388 (W.D. Ky. 2018) (electrical engineer's "knowledge and experience qualify him to be able to offer opinions on regenerative braking" despite lack of specific experience with that type of technology). *See Laski v. Bellwood*, 132 F.3d 33 (6th Cir. 1997) (district court abused discretion excluding testimony of causation experts who were "only" medical specialists and not experts in biomechanics or accident reconstruction because "[r]equiring such specialization thwarts the goals and purposes of the Federal Rules"), *citing DaSilva v. American Brands, Inc.*, 845 F.2d 356, 361 (1st Cir. 1988) (trial court properly permitted mechanical engineer to give an opinion on the safety of the design

of an industrial mixing machine even though the witness had no design experience with the particular machine at issue).

Where, as here, it is alleged that Manufacturers failed to report and stop suspicious orders, it is relevant for the fact-finder to determine whether they could have identified suspicious orders by applying reasonable analytical models to data available to them. Under the applicable regulations, the size of an order alone—irrespective of any other factor—is enough to trigger the duty to report the order as suspicious. *See* Ex. C, Letter from DEA to Registrants dated December 27, 2007 (US-DEA-00017912); Kyle Wright Dep. (03/04/19), Dkt # 1972-13 at 352:18-24. Manufacturers' and distributors' SOM systems all used metrics that focused on the size of the order.

It is of no moment that Keller offers no opinion on the question whether particular orders were "suspicious" as that term is defined in the governing regulation. An expert is not required to "know answers to all the questions a case presents." *Jahn v. Equine Servs., PSC*, 233 F.3d 382, 390 (6th Cir. 2000). Keller's analysis will help the fact-finder understand what would have happened if Manufacturers had applied any of the various metrics to the data they had available. Manufacturers do not suggest that the fact-finder would be competent to perform anything like the enormous "number crunching" exercise performed by Keller.

Manufacturers quarrel with whether Keller used appropriate metrics. The CSA and the regulations thereunder do not specify what metrics are to be used to identify suspicious orders; rather, it is the duty of registrants to design effective systems. Defendants claim to have met that obligation through SOM programs that used mathematical metrics to flag orders. They can hardly complain that Keller used the same metrics used by defendants in their own programs. To the extent Manufacturers object to Keller having used multiple metrics, or metrics other than the ones they prefer, their objection goes to the weight of the evidence, not its reliability. *Contract Design Grp., Inc. v. Wayne State Univ.*, 635 F. App'x 222, 237 (6th Cir. 2015) ("Ultimately, [the expert's] failure to consider certain

factors … could reasonably have been understood to go to weight rather than admissibility"); *In re Fosamax*, 2013 WL 1558690 at *9 (data-mining expert testimony admitted even where "no reasonable standard of care … required Defendant to conduct data-mining").

Likewise, it is immaterial that Keller cannot opine whether any Manufacturer should have used some or all of the available metrics as part of a suspicious order monitoring system, whether any order identified by those metrics should have been reported to the DEA, or whether any such order was "suspicious" within the meaning of the CSA. Her analysis and number crunching will be helpful to the fact-finder in deciding those questions for itself.[4]

Moreover, separate and apart from providing valuable data with respect to the Manufacturers' compliance (or lack thereof) with their statutory and regulatory duties, Keller's analysis also provides important and valuable information about the causal relationship between Manufacturers' failures to identify and report suspicious orders and the harms that actually occurred. Keller's analysis establishes that diversion was not merely a hypothetical concern: the data show clear evidence of doctors writing, and pharmacies filling, prescriptions in Summit and Cuyahoga Counties of unusual volume, frequency or pattern. For example Dr. Yang's almost 40,000 prescriptions in a single year could not have been the result of actual consultations with actual patients—Keller's analysis shows that it would not have physically been possible for Dr. Yang to meet with so many patients and determine that an opioid prescription was appropriate—particularly when he was so busy entertaining Manufacturers' sales reps. Her analysis thus provides a valuable link between the suspicious patterns that Defendants failed to report and actual diversion that occurred in the Plaintiff counties.

B. Keller's Analysis Need Not Consider "Due Diligence"

Manufacturers object that Keller fails to include in her analysis consideration of the "due diligence" that was supposedly part of their SOM programs. Their argument, however, is founded on

[4] For the same reason, Keller's opinions are not misleading and are therefore not inadmissible under Fed. R. Evid. 403.

a fundamental mischaracterization of the role of due diligence under the CSA. According to Manufacturers, an order flagged by metrics alone cannot be deemed "suspicious" until *after* they have completed an investigation. To the contrary, due diligence is not a prerequisite to a determination that an order is suspicious; rather, due diligence is something performed, if at all, only *after* a suspicious order is discovered. "Once a distributor has reported a suspicious order, it must make one of two choices: decline to ship the order, or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order." *Masters Pharm.*, 861 F.3d at 212-13. *See also* Ex. C, Letter from DEA to Registrants dated December 27, 2007 (US-DEA-00017912). Put another way, if a Manufacturer determines through due diligence that a suspicious order is not likely to be diverted, that does not mean it was not suspicious in the first place; rather, it means that the order, despite being suspicious, is not likely to be diverted and so may be shipped. Furthermore, Manufacturers have a duty to report suspicious orders as soon as they are "discovered." Manufacturers are not permitted to delay reporting suspicious orders pending the results of their alleged "due diligence." Nor are they permitted to fail to report a suspicious order on the ground that their alleged "due diligence" established that the order was not likely to be diverted. The duty to report orders of unusual size, frequency, or pattern when discovered—regardless of any due diligence that Manufacturers might later choose to perform—is critical to the ability of the DEA to perform its own independent, unbiased investigation of such orders.

The testimony of DEA representatives selectively quoted by Manufacturers in footnote 10 of their brief is not inconsistent with the view that under the plain language of the applicable regulation due diligence is irrelevant to the determination whether an order is suspicious. *See* Joseph Rannazzisi Dep. (05/15/19), Dkt # 1969-21 at 422:14-423:2 ("Q: Who do they report these suspicious orders to? A: [DEA]. Q: Do they simply report them or does it have any implications for whether or not they ship them? … A: We—we took the position that if you're maintaining effective controls against

diversion and you have a suspicious order, you wouldn't ship that because by definition, it's suspicious, without doing due diligence to make a determination and resolving suspicions").

Moreover, even if "due diligence" were a factor that might appropriately be considered, Keller's failure to do so would only go the weight to be accorded her opinions, not the reliability of her methodology. *Contract Design Grp.,* 635 F. App'x at 237; *Universal Surveillance Corp. v. Checkpoint Sys., Inc.*, No. 5:11-CV-1755, 2015 WL 6082122, *15 (N.D. Ohio Sept. 30, 2015) (Cohen, Special Master). Regardless of what Defendants might have learned through the due diligence they might have performed, Keller's analysis provides valuable insight into the number of orders of unusual size and what attention to those orders would have revealed.

II. IQVIA DATA IS RELIABLE

Manufacturers argue that Keller's opinions are unreliable because the IQVIA data on which she relies is unreliable and/or was not necessarily in their possession. It is of no moment that Keller is unable to say which, if any, of Manufacturers actually possessed IQVIA. All of the Manufacturers had access to IQVIA data, and many of them purchased and relied on it in their business for marketing and other purposes. Manufacturers and distributors are experts in this field, and if they rely on IQVIA data, then that fact alone is sufficient to establish both the reliability of the data and the appropriateness of Keller's use of it. *See* Fed. R. Evid. 703. Plaintiffs need not prove, and Keller need not opine, that Manufacturers had an obligation to acquire IQVIA data for use in their suspicious order monitoring programs. It is beyond dispute that the data was available to any Manufacturer who wanted it and that it could have been used for suspicious order monitoring. *See* Ex. D, Purdue Order Monitoring System Presentation, at 5 (IMS, which is cited in the presentation, is now IQVIA).

Manufacturers' complaints regarding how the data works and how it is maintained goes to the weight of Keller's opinions, not its admissibility. Keller used IQVIA data that Allergan purchased in 2018 for this litigation. The fact that IQVIA is no longer able to re-create the precise historical reports

that Manufacturers previously received or could have obtained is not a reason to preclude Keller from using the best data available. There is no reason to suppose that an application of Keller's analysis to reconstructed historical reports would produce materially different results.

III. KELLER'S ESTIMATE OF THE VOLUME OF MALLINCKRODT "PECULIAR" ORDERS SOLD TO PHARMACIES IN PLAINTIFFS' COUNTIES IS RELIABLE

In the periods 2003 and 2005 through 2017, Mallinckrodt fulfilled over 58,500 opioid orders that Mallinckrodt itself had identified as "peculiar."[5] Mallinckrodt did not ship those opioids to any distributors in Summit and Cuyahoga Counties—because none are located there. Using her data-mining expertise, however, Keller used chargeback data to estimate what portion of the orders identified as "peculiar" wound up in Summit and Cuyahoga. In order to make that estimate, she identified Summit and Cuyahoga pharmacies that purchased an opioid product from a distributor within thirty days of a transaction that Mallinckrodt deemed "peculiar" where the purchase involved the same distributor and the same opioid product. Keller chose a 30-day period because (i) many of the SOM algorithms used a 30-day lookback and (ii) chargeback requests were submitted by some distributors on a monthly basis. Ex. E, Keller Dep., Dkt # 1963-13 at 370:9-19. Using this analysis, Keller was able to determine that of the 58,500 peculiar transactions, 2,860 involved distributors that shipped the same opioid product purchased in the peculiar transaction to buyers in either Summit County or Cuyahoga County within 30 days. Keller Rep. Dkt. # 2000-7at 84.

Keller does not suggest that it is possible to determine precisely how many individual pills in a "peculiar" order found their way to Summit and Cuyahoga Counties. Nonetheless, information regarding the number of peculiar transactions that involved distributors that shipped the same opioid

[5] Keller Rep. Dkt. # 2000-7at 83-84, *citing* MNK-T1_0008592627 (this exhibit is not attached as it is 6,210 pages long; plaintiffs will file a copy should there be any dispute about it). Plaintiffs note that, in order to evade the requirements of the CSA, Manufacturers used euphemisms like "peculiar" when their SOM metrics flagged orders of unusual size, frequency, or pattern. *See, e.g.*, Ex. D, Purdue Order Monitoring System Presentation, at 7 ("Outlets with orders outside normal range based on algorithm" referred to as "Potential Problematic Outlets").

product purchased in the peculiar transaction to buyers in Summit or Cuyahoga Counties within 30 days is relevant and will assist the trier of fact. Where, as here, it is certain that some portion of the defendant's "peculiar" sales wound up in Summit and Cuyahoga, and the uncertainty is as to the precise amount, it is permissible for an expert to make reasonable assumptions in order to arrive at an estimate. *See In re Settlement Facility Dow Corning Tr.*, 754 F. App'x 409, 416 (6th Cir. 2018); *Monroe v. FTS USA, LLC*, 860 F.3d 389, 400 (6th Cir. 2017) (no error in relying on future financial projections based on extrapolations from claims data using a series of assumptions). *See also Innovation Ventures, LLC v. Custom Nutrition Labs., LLC,* 912 F.3d 316, 345 (6th Cir. 2018) (future lost profits may be estimated based on assumptions).

In estimating what portion of "peculiar" orders found their way to Summit and Cuyahoga Counties, Keller's assumed that purchases by pharmacies in Summit and Cuyahoga made in reasonable temporal proximity to a "peculiar" order came from that order. That was a perfectly reasonable assumption in light of the fact that many of the defendants' SOM algorithms used a 30-day lookback and chargeback requests were submitted by some distributors on a monthly basis. Ex. E. Manufacturers' attack on her assumptions goes to the weight and not the admissibility of her opinion. *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 531 (6th Cir. 2008). *See also Robinson v. Suffolk County Police Dept.*, 544 F. App'x 29, 32 (2d Cir. 2013) ("Expert testimony should be excluded where it is speculative or conjectural, but arguments that the expert's assumptions are unfounded go to the weight, not the admissibility, of the testimony").

IV. KELLER'S METHOD FOR COUNTING ORDERS THAT COULD HAVE BEEN STOPPED DESPITE JANSSEN BEING A "SMALL LABELER" IS RELIABLE

Manufactures argue that Keller's "small labeler" opinion is unreliable because it is based on a hypothetical. She assumes, as she was asked to assume: (i) that Janssen—which she calculates had a market share of less than one percent in Summit and Cuyahoga Counties—reported to the authorities the suspicious prescribers flagged by her analysis and (ii) that each such prescriber would have been

stopped from prescribing all opioids (not just Janssen's) immediately after being reported. Using those assumptions, Keller was able to analyze the data to provide a picture of what would have happened if Janssen had complied with its regulatory obligations. Specifically, she was able to estimate the volume of all manufacturers' prescriptions (not just Janssen's) that could have been stopped if those prescribers had been reported to the authorities.

The fact that Keller relies on a hypothetical hardly undermines the reliability of her opinion. Experts testify based on hypotheticals all the time. *See* Fed. R. Evid. 703, Advisory Committee Note ("Facts or data upon which expert opinions are based may, under the rule, be derived from … the familiar hypothetical"). It is true, of course, "that expert testimony should be excluded if it relies on facts that no jury could accept, or relies on the rejection of facts that any jury would be required to accept," *Lee v. Smith & Wesson Corp.*, 760 F.3d 523, 527 (6th Cir. 2014), but Keller's testimony is based on an assumption that Plaintiffs are prepared to prove is reasonable at trial.[6]

CONCLUSION

For the foregoing reasons, this Court should deny Defendants' motion to exclude Lacey Keller's opinions and proposed testimony.

Dated: July 31, 2019

Respectfully submitted,

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[6] The assumption is hardly a stretch given some of the examples cited in Keller's report. Ex-doctor Harper surrendered his license in May 2012 after state and federal authorities determined he was illegally prescribing opioids. Keller Rep. Dkt. # 2000-7 at 46. Ex-doctor Lundeen surrendered his license to the Ohio State Medical Board in 2011 on the ground that he had overprescribed opioids. *Id.* at 43. Ex-doctor Zaidi fled to Pakistan in 2014 when he was indicted on charges that included charges of conspiracy to distribute controlled substances, and his Ohio medical license was revoked. *Id.* at 50.

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